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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,935	11/01/2001	Robert Eric Montgomery	P1088US011	9955
53096	7590	06/07/2007	EXAMINER	
DISCUS DENTAL IMPRESSIONS, INC.			JAGOE, DONNA A	
8550 HIGUERA STREET			ART UNIT	PAPER NUMBER
CULVER CITY, CA 90232			1614	
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/039,935	MONTGOMERY, ROBERT ERIC
Examiner	Art Unit	
Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 30 December 2006.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 56-58,61-65,67-76 and 78-81 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 56-58,61-65,67-76 and 78-81 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. ____ .
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ .
5) Notice of Informal Patent Application
6) Other: ____ .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 30, 2006 has been entered.

Applicants' arguments filed December 30, 2006 have been fully considered and they are deemed to be persuasive regarding previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

However, upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 56-58, 61-65 and 67-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In particular, "including a chelating agent" (present claims 56 and 71) is a concept that was not present in the specification as originally filed. Therefore it is considered new matter. Applicants are advised that the issue here is not whether particular instances of **calcium** chelating agent are found, but rather whether the concept of **any** chelating agent was present in the specification as originally filed. The Examiner contends that support for any chelating agent was not present in the specification as originally filed. The specification as originally filed contains the following disclosures concerning chelating agents:

- (i) "...The matrix comprises a thickening agent, an agent for stabilizing the hydrogen peroxide-containing compound, a pH adjusting agent 25 and a calcium chelating agent." (page 4, lines 23-25);
- (ii) "...a calcium chelating agent is included in the composition to prevent precipitation of calcium ions. (Table 1-4)" (page 6, lines 1-4);
- (iii) "...examples of calcium chelating agents include any of the calcium chelating agents known in the art" (page 6, lines 8-9);
- (iv) "...calcium chelating agents may prevent this precipitation of calcium ions with the associated observed improvement of tooth bleaching effect." (page 6, lines 17-18);

(v) "...more particularly 8-9.5 that includes a calcium chelating agent " (page 7, line 11).
(vi)"... positive effect of the calcium chelating agent on tooth bleaching..." (page 14, line 1)

The above disclosures, however, do not provide adequate support for any chelating agent. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention.

Lockwood v. American Airlines, Inc., 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The Examiner is guided in his opinion that Applicant has not adequately described the presently claimed subject matter by the MPEP at § 2163 - 2163.05. In particular, while Applicant's specification as originally filed contained a teaching of calcium chelating agents. Applicants now claim a chelating agent. Because such represents a genus that were not previously set forth or that would have been immediately envisaged by one skilled in the art from the specification as originally filed. "A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996)"(emphasis added), see MPEP § 2163(I)(A). Also, "See also *In re Smith*. 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ('Whatever may be the viability of an inductive-deductive approach to arriving at a claimed subgenus, it cannot be said that such a subgenus is necessarily

described by a genus encompassing it and a species upon which it reads.' (emphasis added)).", see MPEP § 2163.05(II).

Considering the teachings provided in the specification as originally filed, the Examiner finds that Applicants have failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth for the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicants had possession of the concept of a "chelating agent". A chelating agent that has two coordinating atoms is called bidentate; one that has three, tridentate; and so on. EDTA, or ethylenediaminetetraacetate, one of the claimed "chelating agents" is a common hexadentate chelating agent. There is no teaching in the instant specification as to how one would choose a chelating agent, other than the calcium chelating agents set forth as in (i)-(vi) above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 81 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding the "mixing baffle" of claim 81, the claim states "The dosage delivery unit of claim 78 wherein the static mixer includes a mixing baffle". It is unclear to the Examiner how the "mixing baffle" differs from the static mixer. Turning to the instant specification on page 7, lines 22-24, it states that the mixing of the two components can

be readily achieved using a multi-component tube containing a baffle, otherwise known in the art as a static mixer". The way the claim is stated, one is led to believe that the baffle is a separate component comprised in the static mixer, however the instant specification describes it as one and the same. Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 56-58, 61-65, 67-76 and 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christina-Beck et al. U.S. Patent No. 5,766,574.

Christina-Beck et al. teach a dual component whitening dentifrice composition (see abstract). The peroxide is *inter alia* sodium percarbonate (a hydrogen peroxide-containing compound) (column 3, lines 11-12) and further comprises thickeners, such as block copolymers having a molecular weight of 4000 (column 3, lines 47-67), water

in an amount of from 5 to 30% (column 3, lines 42-46), and chelating agents such as sodium acid pyrophosphate (column 4, lines 1-10). It does not teach a stabilizing agent, however, it is noted that the stabilizing agent instantly claimed in claim 63 is sodium acid pyrophosphate, which is present in the composition of Christina-Beck as a chelating agent. "Products of identical chemical composition (i.e. sodium acid pyrophosphate) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. a stabilizing agent) are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a *prima facie* case of unpatentability of Spada's polymer latexes for lack of novelty.").

The pH of the formulation is in the range of 5 to 8, which overlaps and partially encompasses claims 58 (pH greater than 5.5), claim 67 (pH within a range of between 6 and 10), claim 68 (pH within a range of between 7 and 10) and claim 69 (pH within a range of between 8 and 9.5).

Christina-Beck et al. differs in that it does not teach an alkaline pH-adjusting agent per se. However, the pH of the dentifrice partially overlaps and encompasses the pH range of the instant claimed dosage delivery unit as noted above. The criticality of the specific alkaline pH-adjusting agents has not been disclosed. In the absence of any

criticality and/or unexpected results of the instantly claimed alkaline pH-adjusting agents of claim 62, the instant invention is considered obvious.

Christina-Beck et al. does not teach the amount of water to be at least 70% water by weight, based on the weight of the mixture (claim 61). It teaches water in the peroxide component in an amount between 5 – 30% (column 3, lines 42-46) and in the abrasive component in an amount between 10 and 20% (column 4, lines 40-41) to total about 15 to 50% water. As anyone of ordinary skill in the art will appreciate, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find *workable* conditions generally involves no more than the application of routine skill in the art of chemical engineering. See, only as exemplary, the dicta of *In re Aller* 105 USPQ 233. Similarly, the determination of *optimal* values within a disclosed range is generally considered obvious. See, only as exemplary, the dicta of *In re Boesch* 205 USPQ 215. For these and other self-evident reasons, it would have been obvious to add water greater than 70%.

Regarding the static mixer of the device, Christina-Beck et al. differs in that there is not a mixing baffle/static mixer disclosed, however, the dual component composition is "maintained separate from the other until dispensed and combined for application to teeth requiring whitening" (see abstract). The mixing of the two components takes place on the toothbrush. Although there is not a mixing baffle, it would have been made obvious to one of ordinary skill in art at the time it was made to have used a dispenser with a mixing baffle motivated by a desire to keep incompatible components separate

until use and simultaneously mix and deliver the two components in substantially equal amounts immediately prior to use.

Response to Arguments

Applicant's arguments with respect to claims 56-58, 61-65, 67-76 and 78-81 have been considered but are moot in view of the new ground(s) of rejection above.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Donna Jagoe
Patent Examiner
Art Unit 1614

June 4, 2007